

REMARKS/ARGUMENTS

In the Office Action, all of the pending claims are rejected. In particular, Claims 5, 12, 41, 46, 49, 50, 53, 54, and 57 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 1, 3-8, 10-24, 37 and 39-42 are rejected under 35 U.S.C. §103(a) over U.S. Patent No. 5,919,147 to Jain ("Jain") in view of U.S. Patent No. 5,010,892 to Colvin et al. ("Colvin"), U.S. Patent No. 6,712,771 to Haddock et al. ("Haddock"), and U.S. Patent No. 6,033,359 to Doi ("Doi"). Moreover, Claims 44-57 are rejected under 35 U.S.C. §103(a) over Jain in view of Colvin, Haddock, and Doi and further in view of U.S. Patent No. 6,450,977 to Baxter-Jones.

As explained in further detail below, Applicant has amended independent Claims 1, 7, 24, and 37 to further distinguish the cited references. Claims 5, 12, 15, 19, and 46, 49, 53, and 57 have been amended for clarification, and Claims 44, 47, 51, and 55 have been cancelled. In light of the amendments and subsequent remarks, Applicant respectfully requests reconsideration and allowance of the claims.

Rejection under §112, ¶1

The Examiner rejects Claims 5, 12, and 41 for allegedly failing to comply with the written description requirement because "the original disclosure does not appear to support inward facing surfaces of the legs in the embodiment of figures 14-18 being in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit." Applicant continues to disagree with the rejection, as Claims 5, 12, and 41 are supported by the specification. For example, page 10, lines 23-26 of the present application clearly states that "when the measurement assembly is retracted, the legs are relaxed and reside adjacent to one another so that the legs may be retracted within the exterior conduit" (emphasis added). Thus, the term "adjacent" was used to describe that the legs are flush to one another, and the only difference between the embodiment shown in FIGS. 1-13 and FIGS. 14-18 is that the distal ends of the legs are coupled together in FIGS. 14-18. The specification does not disclose that there are any other differences between the embodiments. In addition, FIG. 18 of the present application shows the legs displaced from the

exterior conduit, wherein portions of the legs proximate to the proximal and distal ends are in flush contact, such that as the legs are retracted into the exterior conduit, the legs would lie flush to one another along their entire length. The specification does not teach or suggest otherwise. Therefore, Applicant respectfully submits that the rejection of Claims 5, 12, and 41 under §112, ¶1, is overcome.

Claims 46, 49, 53, and 57 have been amended for clarification to recite that the exterior conduit comprises inner and outer surfaces, and the distal end of the exterior conduit comprises a lip protruding from the inner surface that is configured to engage the detents defined in the legs. As such, Applicant submits that the rejection of Claims 46, 49, 53, and 57 under §112, ¶1, is overcome.

Rejection under §103(a)

In Applicant's previous response, independent Claims 1, 7, 24, and 37 were amended to recite that the measurement markers formed on the exterior conduit are configured to provide information regarding length of a target site and that the lumen facing surface of each of the legs includes a plurality of measurement markers defined therein that are configured to provide information regarding a diameter of the target site. Although it appears that the amendment was persuasive in overcoming the previously cited references, the Examiner now relies on Doi as disclosing legs having a plurality of measurement markers on their lumen facing surfaces. Doi discloses a length-measuring tool that includes strips (4) that are configured to spread outwardly via bendable portions (5, 6, 7) into a cross-shape. Each strip includes a scale (8) on a length-measuring section (9) that provides information regarding the size of a diseased part.

With respect to dependent Claims 44-57, which were added in Applicant's previous response and relate to the engagement of the outer conduit and inner conduit for determining the diameter of a target segment, the Examiner relies on Baxter-Jones. Baxter-Jones discloses a device for measuring a cervix that includes a hollow member (1104), an elongated member (1102), and a slidable indicator (1116). The device also includes a measuring scale (1118) and respective detents (1130). The slidable indicator is configured to slide along the elongated

member and engage detents in order to provide a length of the cervix using the measurement scale.

In light of the new rejection, Applicant has amended independent Claims 1 and 37 to recite that the exterior conduit is configured to engage the measurement markers of the legs to provide an indication of a diameter of the target segment. Similarly, Claims 7 and 24 have been amended to recite displacing the exterior conduit and measurement assembly relative to one another such that the exterior conduit engages the measurement markers of the legs. For example, FIG. 11 of the present application illustrates that the legs include detents (360) that engage with a lip (170) extending from the exterior conduit.

In contrast, the slidable indicator of Baxter-Jones is clearly not an exterior conduit longitudinally extending between proximal and distal ends, as recited by independent Claims 1, 7, 24, and 37. Rather, the slidable indicator of Baxter-Jones is simply a collar that is configured to slide over the elongated member. Therefore, Baxter-Jones is distinguishable from Claims 1, 7, 24, and 37 for at least this reason.

Moreover, Baxter-Jones does not teach or suggest that the device provides an indication of a diameter. Conversely, the slidable indicator includes a measuring scale for determining length. In fact, Baxter-Jones discloses that the device is used to measure the length of the cervix rather than the diameter. Thus, Baxter-Jones does not teach or suggest an exterior conduit that is configured to engage the measurement markers of the legs to provide an indication of a diameter of the target segment, as recited by the claimed invention.

In addition, there is no motivation to modify Doi or any of the cited references to include an exterior conduit that is configured to engage the measurement markers of the legs to provide an indication of a diameter of the target segment. The Examiner relies on Doi as disclosing legs having a plurality of measurement markers on their lumen facing surfaces that are capable of providing information regarding a diameter of a target segment. However, the measurement indicators of Doi include scales on each of the strips, wherein at least one one of the four length-measuring sections bends outwardly within a visual field. Thus, the measurement indicators on the outer surface of the strips of Doi, which are used to determine a diameter, would be incapable of functioning with the slidable indicator of Baxter-Jones, which is used to determine length.

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And, there is simply no motivation to combine the references based on the fact that the device of Doi is used to measure a diameter of a target segment and the device of Baxter-Jones is employed to measure the length of a cervix. Therefore, there is no motivation or suggestion to modify Doi to include an exterior conduit that is configured to engage legs having measurement indicators on their lumen-facing surfaces in order to determine a diameter of a target segment.

In view of the remarks and amendments presented above, it is respectfully submitted that Claims 1, 3-8, 10-24, 37, 39-42, 45, 46, 48-50, and 52-54 of the present application are in condition for allowance. It is respectfully requested that a Notice of Allowance be issued in due course. The Examiner is requested to contact Applicants' undersigned attorney to resolve any remaining issues in order to expedite examination of the present application.

The patentability of the independent claims has been argued as set forth above and thus Applicants will not take this opportunity to argue the merits of the rejection with regard to the dependent claims. However, Applicants do not concede that the dependent claims are not independently patentable and reserve the right to argue the patentability of the dependent claims at a later date if necessary.

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CONCLUSION

In view of the amended claims and remarks presented above, it is respectfully submitted that all of the present claims of the present application are in condition for immediate allowance. It is therefore respectfully requested that a Notice of Allowance be issued. The Examiner is encouraged to contact Applicant's undersigned attorney to resolve any remaining issues in order to expedite examination of the present application.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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